



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** Christian P. Larsen et al. **Examiner:** Not yet known  
**Serial No.:** 10/057,288 **Group Art Unit:** 1644  
**Filed:** January 25, 2002 **Docket No.:** D0136NP/30436.58USU1  
**Title:** METHODS OF INDUCING ORGAN TRANSPLANT TOLERANCE AND CORRECTING HEMOGLOBINOPATHIES

**CERTIFICATE UNDER 37 CFR §1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 27, 2004.

By: *Renato Marco P. Domingo*  
Name: Renato Marco P. Domingo

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**(37 C.F.R. § 1.97(b)(3))**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is being filed herein as a supplement to Applicant's July 31, 2002, January 15, 2003, and June 13, 2003, Information Disclosure Statements which were submitted under 37 C.F.R. §1.97(b)(3) before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 251-265 as set forth in the Form 1449 are included herein.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. These are as follows:

- International Published Application No. WO94/01547 published January 20, 1994 – Exhibit 251

- International Published Application No. WO95/06481 published March 9, 1995 – **Exhibit 252**
- International Published Application No. WO95/28957 published November 2, 1995 – **Exhibit 253**
- Bluestone, Jeffrey A., “New Perspectives of CD28-B7-Mediated T Cell Costimulation,” *Immunity*, 1995, 2:555-9 – **Exhibit 254**
- Bluestone, J. A., “Costimulation and its role in organ transplantation,” *Clin. Transplantation*, 1996, 10:104-9 – **Exhibit 255**
- Chen, Fang-An et al., “Human Antibody Response in Human Peripheral Blood Leukocyte/Severe Combined Immunodeficient Chimeric Model is Dependent on B and T Cell Costimulation via CD40/CD40 Ligand,” *Journal of Immunology*, 1995, 155:2833-40 – **Exhibit 256**
- Durie, Fiona H. et al., “Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40,” *Science*, 1993, 261:1328-30 – **Exhibit 257**
- Durie, Fiona H. et al., “Antibody to the Ligand of CD40, gp39, Blocks the Occurrence of the Acute and Chronic Forms of Graft-vs-Host Disease,” *Journal of Clinical Investigation*, 1994, 94:1333-8 – **Exhibit 258**
- Griggs, Nathan et al., “Contribution of CD28/CTLA4/B7 and gp39/CD40 Costimulation Pathways in Clonal Expansion and Functional Acquisition of Self Reactive T Cells,” *Journal of Cellular Biochemistry*, 1995, Supplement, p. 141, C2-427 – **Exhibit 259**
- Jenkins, Marc K. et al., “CD28 Delivers a Costimulatory Signal Involved in Antigen-Specific IL-2 Production by Human T Cells,” *Journal of Immunology*, 1991, 147:2461-6 – **Exhibit 260**
- Lenschow, Deborah J. et al., “Inhibition of Transplant Rejection Following Treatment with Anti-B7-2 and Anti-B7-1 Antibodies,” *Transplantation*, 1995, 60:1171-8 – **Exhibit 261**
- Rossini, Aldo A. et al., “Induction of Immunological Tolerance to Islet Allografts,” *Cell Transplantation*, 1996, 5:49-52 – **Exhibit 262**

- Roy, Meenakshi et al., "Studies on the interdependence of gp39 and B7 expression and function during antigen-specific immune response," *European Journal of Immunology*, 1995, 25:596-603 – **Exhibit 263**
- Schaub, M. et al., "Synergistic effect of CD40L/CD40 and CD28/B7 Blockade in murine EAE," *Journal of Allergy and Clinical Immunology*, 1997, 99:5206, Abstract 843 – **Exhibit 264**
- Tang, Aimin et al., "Suppression of Murine Allergic Contact Dermatitis by CTLA4Ig: Tolerance Induction of Th2 Responses Requires Additional Blockade of CD40-Ligand," *Journal of Immunology*, 1996, 157:117-25 – **Exhibit 265**

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that the references have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Applicants invite the Patent Office to request additional information if necessary. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Christian P. Larsen, et al.  
Serial No. 10/057,288  
Filed: January 25, 2002  
Page 4



No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

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**Docket:** D0136NP/30436.58USU1  
**Title:** METHODS OF INDUCING ORGAN TRANSPLANT TOLERANCE AND CORRECTING HEMOGLOBINOPATHIES

**CERTIFICATE UNDER 37 CFR 1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 27, 2004.

By: *Renato Marco P. Domingo*  
Name: Renato Marco P. Domingo

55 S. Lake Avenue, Suite 710  
Pasadena, California 91101  
February 27, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

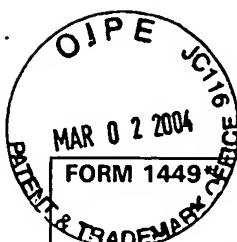
We are transmitting herewith the attached:

- Transmittal sheet, in duplicate, containing Certificate under 37 CFR §1.8
- Supplemental Information Disclosure Statement (37 C.F.R. §1.97 (b)(3))
- Form 1449 (Information Disclosure Statement)
- Exhibits 251-265
- Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

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FORM 1449

**INFORMATION DISCLOSURE STATEMENT  
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number	Application Number
D0136NP/30436.58USU1	10/057,288
Applicants	
Christian P. Larsen et al.	
Filing Date	Group Art Unit
January 25, 2002	1644

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
.						
.						

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
.	WO94/01547 (Exhibit 251)	01/20/94	PCT				X
.	WO95/06481 (Exhibit 252)	03/09/95	PCT				X
.	WO95/28957 (Exhibit 253)	11/02/95	PCT				X
.							

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

.	Bluestone, Jeffrey A., "New Perspectives of CD28-B7-Mediated T Cell Costimulation," <i>Immunity</i> , 1995, 2:555-9 (Exhibit 254)
.	Bluestone, J. A., "Costimulation and its role in organ transplantation," <i>Clin. Transplantation</i> , 1996, 10:104-9 (Exhibit 255)
.	Chen, Fang-An et al., "Human Antibody Response in Human Peripheral Blood Leukocyte/Severe Combined Immunodeficient Chimeric Model is Dependent on B and T Cell Costimulation via CD40/CD40 Ligand," <i>Journal of Immunology</i> , 1995, 155:2833-40 (Exhibit 256)
.	Durie, Fiona H. et al., "Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40," <i>Science</i> , 1993, 261:1328-30 (Exhibit 257)
.	Durie, Fiona H. et al., "Antibody to the Ligand of CD40, gp39, Blocks the Occurrence of the Acute and Chronic Forms of Graft-vs-Host Disease," <i>Journal of Clinical Investigation</i> , 1994, 94:1333-8 (Exhibit 258)
.	Griggs, Nathan et al., "Contribution of CD28/CTLA4/B7 and gp39/CD40 Costimulation Pathways in Clonal Expansion and Functional Acquisition of Self Reactive T Cells," <i>Journal of Cellular Biochemistry</i> , 1995, Supplement, p. 141, C2-427 (Exhibit 259)
.	Jenkins, Marc K. et al., "CD28 Delivers a Costimulatory Signal Involved in Antigen-Specific IL-2 Production by Human T Cells," <i>Journal of Immunology</i> , 1991, 147:2461-6 (Exhibit 260)
.	Lenschow, Deborah J. et al., "Inhibition of Transplant Rejection Following Treatment with Anti-B7-2 and Anti-B7-1 Antibodies," <i>Transplantation</i> , 1995, 60:1171-8 (Exhibit 261)
.	Rossini, Aldo A. et al., "Induction of Immunological Tolerance to Islet Allografts," <i>Cell Transplantation</i> , 1996, 5:49-52 (Exhibit 262)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.



<b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b> (Use several sheets if necessary)		Docket Number D0136NP/30436.58USU1	Application Number 10/057,288
		Applicants Christian P. Larsen et al.	
		Filing Date January 25, 2002	Group Art Unit 1644

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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